



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/534,469      | 11/16/2005  | Shlomo Margel        | 4110-40             | 7014             |

23117 7590 01/25/2008  
NIXON & VANDERHYE, PC  
901 NORTH GLEBE ROAD, 11TH FLOOR  
ARLINGTON, VA 22203

EXAMINER

DAVIS, RUTH A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1651

| MAIL DATE | DELIVERY MODE |
|-----------|---------------|
|-----------|---------------|

01/25/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/534,469

**Applicant(s)**

MARGEL ET AL.

**Examiner**

Ruth A. Davis

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 10-14 and 20-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 15-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 5/05:11/05.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of group I, claims 1 – 9 and 15 - 19 in the reply filed on October 29, 2007 is acknowledged.

Claims 1 – 28 are pending, claims 10 – 14 and 20 – 28 are withdrawn from consideration; claims 1 – 9 and 15 – 19 have been considered on the merits.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1 – 2, 5 – 9 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Marx et al. (US 6552172).

Marx teaches fibrin (organic protein) nanoparticles coupled (or covalently bonded) to agents wherein the agents may be thrombin (col.2, 7) or other pharmaceuticals (col.7).

The reference anticipates the claimed subject matter.

*Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1 – 9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hallahan et al. (US 2003/0219785).

Hallahan teaches a delivery vehicle comprising an active agent and a paramagnetic material, wherein the agent may be thrombin (0013,0018) and the paramagnetic material may be a nanoparticle (0027-0030) made from iron oxide (0137). The nanoparticle may include a linker (or spacer arm) (0027-0031,0144) made from albumin (0148) and additionally pharmaceuticals may also be included.

The reference does not specifically teach the composition wherein the components are covalently bound as claimed, however such bonds were common when the instant components are combined together. Thus, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to make the claimed nanoparticle with a reasonable expectation for successfully obtaining an effective therapeutic nanoparticle composition.

7. Claims 1 – 9 and 15 – 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hallahan in view of Lanza et al. (US 7220401) and Marx.

Hallahan teaches a delivery vehicle comprising an active agent and a paramagnetic material, wherein the agent may be thrombin (0013,0018) and the paramagnetic material may be a nanoparticle (0027-0030) made from iron oxide (0137). The nanoparticle may include a linker (or spacer arm) (0027-0031,0144) made from albumin (0148) and additionally pharmaceuticals may also be included.

Hallahan reference does not specifically teach the composition wherein the components are covalently bound as claimed, however such bonds were common when the instant components are combined together. Thus, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to make the claimed nanoparticle with a reasonable expectation for successfully obtaining an effective therapeutic nanoparticle composition.

Hallahan does not teach the compositions wherein the therapeutic composition is a powder with a gelatin dispersant, liquid, or with other additives. However, at the time of the

claimed invention, it would have been obvious to one of ordinary skill in the art to incorporate the nanoparticle composition of Hallahan into the instant forms as it was routinely practice in the art at the time of the claimed invention. In support, Lanza teaches liquid therapeutic compositions comprising nanoparticles(col.2), Marx teaches additives such as Factor XIII (col.4, 6), and dry and liquid formulations (see throughout, col.6). Thus, as evidenced by the cited references, it would have been well within the purview of one of ordinary skill in the art to incorporate the nanoparticle compositions into the instant forms as a matter of routine experimentation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:  
10/534,469  
Art Unit: 1651

Page 6

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth A. Davis/  
Primary Examiner  
Art Unit 1651

January 16, 2008